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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,419	07/27/2001	William P. Kelleher	CSLL-624	8855

7590 11/30/2006

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EXAMINER	
BEISNER, WILLIAM H	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/916,419	KELLEHER ET AL.	
	Examiner	Art Unit	
	William H. Beisner	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2006 and 20 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,6-21 and 24-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6-21 and 24-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/13/06 has been entered.

Claim Objections

2. Claim 24 is objected to because of the following informalities: Claim 24 depends from cancelled claim 23. The claim will be examined as though it depends from claim 21. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 2, 6-21 and 24-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Instant claims 1, 2, 6-21 and 24-27 recite the following claim limitations: i) "a film formed of a plurality of conjugated polymer molecules and/or ii) the predetermined material is capable of interacting with at least one of the molecules in response to excitation light so as to generate or create a fluorescent signal. With respect to item i) above, review of the originally filed specification fails to provide guidance as to any specific substances which have the ability to generate a signal in response to interacting with a predetermined material that has been excited to interact with the film of molecules. The specification does recite that the molecules can be "conjugated polymer molecules" but again fails to set forth specific molecules that would be capable of functioning as recited in the claim and/or that would be known to one of ordinary skill in the art at the time of filing the instant invention. With respect to item ii) above, while the originally filed specification includes numerous references to the fact that the predetermined material interacts with the film of molecules in response to excitation light wherein the interaction generates a fluorescent signal (See pages 5, 11 and 12 of the instant specification) and the specification lists a number of possible predetermined materials, the specification fails to provide guidance as to any specific combination of predetermined material, excitation light and film molecule that would provide the signal generation of fluorescent light required of the instant claims. Note when discussing the state of the prior art, the instant specification (See pages 1-2) states that the excitation light "induces any fluorescence emitting agent present in the sample to fluoresce". The discussion of the prior art is silent as to any agent, entity and/or microorganism that "interacts" with a film of molecules in response to an excitation light. Also the prior art of the references of Grey et al.(US 5,157,261) and Ligler et al.(US 5,496,700) are both drawn to fluorescence detection systems for the detection of "microorganisms". The reference of Grey et

al. is drawn to the detection of TNT while the reference of Ligler et al. is drawn to the detection of microbiological agents. Neither of these references convey to one of ordinary skill in the art that either of the detected analytes "interact" with a film of molecules "in response to an excitation light". No working examples are provided to provide such missing information. Without such information, one skilled in the art could not predict which predetermined materials from the vast number of possible microorganisms would respond to an excitation light to interact with a film of molecules as required of the instant claims. Furthermore, one skilled in the art would not be capable of determining which "polymer molecules" and/or "conjugated polymer molecules" could be used that would interact with a microorganism to generate a fluorescent signal. In view of this lack of information, one skill in the art would be required to perform undue experimentation to identify any "microorganisms" and/or "polymer molecules" that would be responsive to excitation light and interact to generate or created a fluorescence signal as required of the instant claims. Therefore, one skilled in the art could not make the invention without undue experimentation.

In response to a previous 35 USC 112, first paragraph, rejection, Applicants has submitted evidence (Chen et al.) to establish that the term conjugated polymers was known to one of ordinary skill in the art at the time of filing the instant application and that conjugated polymers would be capable of functioning as recited in the claims and specification and/or that would be known to one of ordinary skill in the art at the time of filing the present invention.

In response, the Examiner is not persuaded because the instant claims recite "said predetermined material is capable of interacting with at least one of said plurality of molecules in response to said excitation light so as to generate a fluorescent signal" and/or "said

predetermined material is capable of binding with at least one of said plurality of conjugated polymer molecules and is responsive to said excitation light so as to generate a fluorescence signal". Review of the submitted evidence as to the use of conjugated polymers in biosensing devices indicates that the predetermined material interacts with a quenching agent complex on the surface of the conjugated polymer and the interaction of the material and complex allows the conjugated polymer to generate a fluorescent signal. Nothing in the disclosure of the submitted evidence would enable the current claim language that the predetermined material responds to the excitation light to bind to the conjugated polymer and/or generate a signal. The interaction between the predetermined material and the conjugated polymer molecules is not corrected recited and/or portrayed in the instant claims.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 2, 6-21 and 24-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 6-21 and 24-27 are indefinite for the following reason. It is not clear what is responsive to the recited excitation light. Does the excitation light cause the predetermined material to "interact" with the film molecules or is the excitation light merely being used to generate a fluorescence emission from fluorescence emitting entities within the detection device.

Does this "interaction" differ from the prior art discussed on pages 1, 2 and 7 of the instant specification? Clarification and/or correction is requested.

In claim 2, "said biological matter predetermined material" lacks antecedent basis. Note claim 1 is silent with respect to "biological matter".

In claim 6, are the recited "a plurality of molecules" the same or different from the "conjugated polymer molecules" of claim 1?

Response to Arguments

7. With respect to the rejection of Claims 1, 3-9 and 11-20 under 35 U.S.C. 103(a) as being unpatentable over Grey et al.(US 5,157,261) in view of Broeng et al.(WO 99/64903), this rejection has been withdrawn in view of Applicants' amendments to the claims and related comments (See pages 10-12 of the response filed 7/13/2006).

8. With respect to the rejection of Claims 1-5, 7-13 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ligler et al.(US 5,496,700) in view of Broeng et al.(WO 99/64903), this rejection has been withdrawn in view of Applicants' amendments to the claims and related comments (See page 12 of the response filed 7/13/2006).

9. With respect to the rejection of Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grey et al.(US 5,157,261) in view of Broeng et al.(WO 99/64903) taken further in view of either Walt et al.(US 5,250,264) or Pinkel et al.(US 5,690,894), this rejection

has been withdrawn in view of Applicants' amendments to the claims and related comments (See pages 12-13 of the response filed 7/13/2006).

10. With respect to the rejection of Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ligler et al.(US 5,496,700) in view of Broeng et al.(WO 99/64903) taken further in view of either Walt et al.(US 5,250,264) or Pinkel et al.(US 5,690,894), this rejection has been withdrawn in view of Applicants' amendments to the claims and related comments (See page 13 of the response filed 7/13/2006).

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

William H. Beisner
Primary Examiner
Art Unit 1744

WHB